## REMARKS

Claims 7-11 were rejected for the same reasons claims 7-11 were rejected in the previous Office Action.

Claims 12-14 were rejected under 35 U.S.C. §112, first paragraph, because the Examiner asserts that, while being enabling for delay of diabetes, claims 12-14 do not reasonably provide enablement for prevention in humans.

### REJECTION OF CLAIMS 7-11

Claim 7 has been amended to cancel "preventing or" and to add "onset of" so that claim 7 reads -- A vaccine for delaying onset of type 1 diabetes mellitus comprising:...-- Thus, as shown by the data in the specification and as admitted by the Examiner, the vaccine of the present invention is submitted to delay the onset of type I diabetes mellitus. Such a delay of the onset of diabetes is not taught or suggested by Muir (USPN 5,891,435). Since claims 8-11 depend from amended claim 7 and have been amended in accordance with claim 7, claims 8-11 are also submitted to be allowable over Muir.

### REJECTION OF CLAIMS 12-14

Claim 12 has been amended to cancel "preventing or" and to add "onset of" so that claim 12 reads -- A method for delaying onset of type 1 diabetes mellitus comprising:...-- Thus, as shown by the data in the specification and as admitted by the Examiner, the method of the present invention is submitted to delay the onset of type I diabetes mellitus. Such a delay of the onset of diabetes is not taught or suggested by Muir (USPN 5,891,435). Since claim 13 depends from amended claim 12, claim 13 is also submitted to be allowable over Muir.

Even the most sophisticated technology at the present time cannot mimic the complicated interactions among cells, tissues and organs that occur in humans and animals. It is respectfully submitted that those skilled in the art are aware that mice have DNA that is approximately 98 per cent identical with human DNA. Thus, mice are considered to be valuable research animals to predict ways of treating human illnesses. For example, much of what is known about the immune system has come form studies with mice. Hence, mouse studies have been utilized for many years to provide suggested human treatments.

Thus, it is respectfully submitted that, based on the information in the specification of the present invention, undue experimentation will not be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Although Couzin states that the presence of antibodies to GAD may indicate a 25% chance of developing diabetes in 5 years, such a statement is based on an individual that was not immunized using GAD, but rather developed the GAD antibodies as a response to an internal condition. As is known to those skilled in the art, vaccination is based on injecting/placing in a human/animal system a small amount of a material that may be utilized to induce a protective response in the human/animal. Typically, introduction of such a material in a human/animal system stimulates the production of protective antibodies or T cells without causing the full-blown disease. Thus, in the present invention, the injection of a small amount of GAD to stimulate a response in a subject that may protect the subject from developing type 1 diabetes mellitus is reasonable, and is not controverted by Couzin.

Thus, claims 7-13 are submitted to be allowable over Muir and Couzin.

In accordance with the foregoing, the claims 7-12 have been amended. Claim 14 has been cancelled without prejudice or disclaimer. Claims 7-13 are pending and under consideration.

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned to attend to these matters.

If there are any additional fees associated with filing of this Amendment, please charge

the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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